BILLING CODE: 4510-29-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Genetic Information Nondiscrimination Act of 2008 Research Exception Notice

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202-693-6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, was enacted on May 21, 2008. Title I of GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (the Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. Sections 101 through 103 of Title I of GINA prevent employment-

based group health plans and health insurance issuers in the group and individual markets from discriminating based on genetic information and from collecting such information.

GINA and the interim final regulations (29 CFR 2590.702-1(c)(5)) provide an exception to the limitations on requesting or requiring genetic testing that allows a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test if all of the following conditions of the research exception are satisfied.

First, the request must be made pursuant to research that complies with 45 CFR part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is entitled (the Participant Disclosure).

Second, the plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits, premium, or contribution amounts.

Third, none of the genetic information collected or acquired as a result of the research may be used for underwriting purposes. Finally, the plan or issuer must complete a copy of the “Notice of Research Exception under the Genetic Information Nondiscrimination Act” and provide it to the address specified in its instructions. The Notice and instructions are available on the Department's website. For additional

substantive information about this ICR, see the related notice published in the *Federal Register* on July 9, 2024 (89 FR 56416).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL-EBSA.

Title of Collection: Genetic Information Nondiscrimination Act of 2008 Research Exception Notice.

OMB Control Number: 1210-0136.

Affected Public: Private sector, Businesses or other for-profits, Not-for-profit institutions.

Total Estimated Number of Respondents: 35.

Total Estimated Number of Responses: 35.

Total Estimated Annual Time Burden: 9 hours.

Total Estimated Annual Other Costs Burden: $199.

(Authority: 44 U.S.C. 3507(a)(1)(D))

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